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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,753	12/21/2001	Ronald G. Udell	SGTI-40565	3723

7590

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Kamran Fattahi, Esq.
LAW OFFICES OF KAMRAN FATTAHI
6345 BALBOA BLVD.
SUITE 330
ENCINO, CA 91316

EXAMINER

MCINTOSH III, TRAVISS C 7

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

10/035,753

Applicant(s)

UDELL ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response To Arguments

The Amendment filed on December 18, 2002 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1, 2, and 11 have been amended.

Claims 6-10 and 13-15 have been canceled.

Arguments submitted affect the instant application by:

Objection to claims 2, 6-10, and 14 and 15 has been withdrawn in light of amendment and claim cancellation.

Rejection of claims 11 and 13-15 under 112 2nd paragraph has been withdrawn in light of amendment and claim cancellation.

Rejection of claims 11-15 under 112 2nd paragraph has been withdrawn in light of amendment and claim cancellation.

Arguments re 102(b) rejection was found to be convincing and the rejection has been withdrawn.

Arguments re 103(a) rejections was found to be convincing and the rejection has been withdrawn.

The text of those section of title 35, US Code not included in this action can be found in a prior Office Action.

An action on the merits of claims 1-5 and 11-12 is contained herein below.

Additionally, as a preliminary matter, the examiner would like to thank applicants for supplying a clean version of all pending claims with the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

Applicant's amendment filed December 18, 2002 introduces new matter into the claims 1 and 11 wherein applicant has amended the range of the hyaluronic acid from between 50,000 – 200,000 daltons to a range of less than 200,000 daltons. Applicant is not entitled to amend the range in this manner as the range of less than 50,000 has not been set forth in the instant application's disclosure. Applicant is required to cancel the new matter.

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Claim Rejections - 35 USC § 103

Claims 1, 2, 11, and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over JP 61000017A to Seikagaku. Because the document is in Japanese, the examiner relies in part on Derwent Acc. No. 1986-045778 for its contents.

The instant application is drawn to composition comprising hyaluronic acid having a dosage of between 35 to 45 mg. and has a molecular weight of less than 200,000 daltons (50,000 – 200,000 preferably) and to a method of improving human skin health by administering said composition.

Seikagaku discloses a hyaluronic acid composition wherein the hyaluronic acid has a molecular weight of between 4,000 – 2,000,000 daltons and the dosage is 25mg – 5g a day (p.o.) (per os, or by mouth). The advantage of the hyaluronic acid composition of Seikagaku is it has tissue restoration effects (thus improving human skin health) (abstract).

In re Peterson (Fed. Cir. 2003). "A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geisler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974)."

Claims 1-5, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seikagaku in view of Yano et al.

Seikagaku discloses the composition as set forth supra. What Seikagaku does not disclose is to add beeswax or rice bran oil to the composition nor to formulate the composition into a soft gelatin capsule.

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Yano et al. teach of a pharmaceutical composition comprising an active ingredient and diluents or carriers wherein the diluents or carriers can be beeswax and rice bran oil. Yano et al. additionally teach that the composition may be in various forms such as soft capsules, hard capsules, granules, and tablets (column 4, line 60 – column 5, line 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Seikagaku and Yano et al. wherein the specified hyaluronic acid of Seikagaku is the active ingredient in the composition of Yano et al. because the limitations as taught by Yano et al. are disclosed as being known in the art of pharmaceutical compositions as common forms of diluents and carriers. One would be motivated to incorporate the hyaluronic acid of Seikagaku into the beeswax and rice bran oil soft gelatin capsule of Yano et al. as to form an oral composition of hyaluronic acid whereby one would avoid the use of topical cosmetics, which frequently contain scents and additives not always pleasing to consumers, and injections, which cause pain and discomfort for the majority of consumers, as the main form of administration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'K. Fonda', written over the printed name.

Kathleen Fonda
Primary Patent Examiner
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Traviss C. McIntosh III
March 7, 2003